

CLAIM LISTING

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Original) A method to elicit an immunogen-specific immune response and a systemic, non-specific immune response in a mammal, comprising administering to said mammal a therapeutic composition by a route of administration selected from the group consisting of intravenous and intraperitoneal, said therapeutic composition comprising:
 - (a) a liposome delivery vehicle; and,
 - (b) a recombinant nucleic acid molecule comprising an isolated nucleic acid sequence encoding an immunogen, said nucleic acid sequence being operatively linked to a transcription control sequence.
2. (Original) The method of claim 1, wherein said route of administration is intravenous.
3. (Original) The method of claim 1, wherein said immunogen is selected from the group consisting of a tumor antigen, an infectious disease pathogen antigen and an allergen.
4. (Original) The method of claim 1, wherein said therapeutic composition further comprises a recombinant nucleic acid molecule having a nucleic acid sequence encoding a cytokine, said nucleic acid sequence being operatively linked to a transcription control sequence.
5. (Original) The method of claim 4, wherein said nucleic acid sequence encoding said immunogen and said nucleic acid sequence encoding said cytokine are in the same recombinant nucleic acid molecule, said nucleic acid sequences being operatively linked to at least one transcription control sequence.
6. (Original) The method of claim 4, wherein said nucleic acid sequence encoding said immunogen and said nucleic acid sequence encoding said cytokine are operatively linked to different transcription control sequences.

7. (Original) The method of claim 4, wherein said cytokine is selected from the group consisting of hematopoietic growth factors, interleukins, interferons, immunoglobulin superfamily molecules, tumor necrosis factor family molecules and chemokines.

8. (Original) The method of claim 4, wherein said cytokine is an interleukin.

9. (Presently amended) The method of claim 4, wherein said cytokine is selected from the group consisting of interleukin-2, interleukin-7, interleukin-12, interleukin-15, interleukin-18, and ~~interferon~~* interferon- γ .

10. (Currently amended) The method of claim 4, wherein said cytokine is selected from the group consisting of interleukin-2, interleukin-12, interleukin-18, and ~~interferon~~* interferon- γ .

11. (Original) The method of claim 1, wherein said transcription control sequences are selected from the group consisting of Rous sarcoma virus (RSV) control sequences, cytomegalovirus (CMV) control sequences, adenovirus control sequences and Simian virus (SV-40) control sequences.

12. (Original) The method of claim 1, wherein said liposome delivery vehicle comprises lipids selected from the group consisting of multilamellar vesicle lipids and extruded lipids.

13. (Original) The method of claim 1, wherein said liposome delivery vehicle comprises multilamellar vesicle lipids.

14. (Original) The method of claim 1, wherein said liposome delivery vehicle comprises cationic liposomes.

15. (Original) The method of claim 1, wherein said liposome delivery vehicle comprises pairs of lipids selected from the group consisting of DOTMA and cholesterol; DOTAP and cholesterol; DOTIM and cholesterol; and DDAB and cholesterol.

16. (Original) The method of claim 1, wherein said liposome delivery vehicle comprises DOTAP and cholesterol.

17. (Original) The method of claim 1, wherein expression of said immunogen in a tissue of said mammal elicits said immunogen-specific immune response in said mammal.

18. (Original) The method of claim 1, wherein administering said nucleic acid molecule and said liposome elicit said systemic, non-specific immune response in said mammal.

19. (Original) The method of claim 1, wherein said mammal is selected from the group consisting of humans, dogs, cats, mice, rats, sheep, cattle, horses and pigs.

20. (Original) The method of claim 1, wherein said mammal is a human.

21. (Original) The method of claim 1, wherein said composition has a nucleic acid:lipid ratio of from about 1:1 to about 1:64.

22. (Original) The method of claim 1, wherein said mammal has cancer and wherein said immunogen is a tumor antigen.

23. (Original) The method of claim 22, wherein said therapeutic composition further comprises a recombinant nucleic acid molecule having a nucleic acid sequence encoding a cytokine, said nucleic acid sequence being operatively linked to a transcription control sequence.

24. (Original) The method of claim 22, wherein said therapeutic composition comprises a plurality of recombinant nucleic acid molecules, each of said recombinant nucleic acid molecules comprising a cDNA sequence amplified from total RNA isolated from an autologous tumor sample, each of said cDNA sequences encoding a tumor antigen or a fragment thereof and being operatively linked to a transcription control sequence.

25. (Original) The method of claim 22, wherein said therapeutic composition comprises a plurality of recombinant nucleic acid molecules, each of said recombinant nucleic acid molecules comprising a cDNA sequence amplified from total RNA isolated from a plurality of allogeneic tumor samples of the same histological tumor type, each of said cDNA sequences encoding a tumor antigen or a fragment thereof and being operatively linked to a transcription control sequence.

26. (Original) The method of claim 22, wherein said cancer is selected from the group consisting of melanomas, squamous cell carcinoma, breast cancers, head and neck carcinomas, thyroid carcinomas, soft tissue sarcomas, bone sarcomas, testicular cancers, prostatic cancers, ovarian cancers, bladder cancers, skin cancers, brain cancers,

angiosarcomas, hemangiosarcomas, mast cell tumors, primary hepatic cancers, lung cancers, pancreatic cancers, gastrointestinal cancers, renal cell carcinomas, hematopoietic neoplasias, and metastatic cancers thereof.

27. (Original) The method of claim 22, wherein said cancer is selected from the group consisting of a primary lung cancer and a pulmonary metastatic cancer.

28. (Original) The method of claim 22, wherein said tumor antigen is from a cancer selected from the group consisting of melanomas, squamous cell carcinoma, breast cancers, head and neck carcinomas, thyroid carcinomas, soft tissue sarcomas, bone sarcomas, testicular cancers, prostatic cancers, ovarian cancers, bladder cancers, skin cancers, brain cancers, angiosarcomas, hemangiosarcomas, mast cell tumors, primary hepatic cancers, lung cancers, pancreatic cancers, gastrointestinal cancers, renal cell carcinomas, hematopoietic neoplasias and metastatic cancers thereof.

29. (Original) The method of claim 22, wherein said tumor antigen is selected from the group consisting of tumor antigens having epitopes that are recognized by T cells, tumor antigens having epitopes that are recognized by B cells, tumor antigens that are exclusively expressed by tumor cells, and tumor antigens that are expressed by tumor cells and by non-tumor cells.

30. (Original) The method of claim 22, wherein said expression of said tumor antigen produces a result selected from the group consisting of alleviation of said cancer, reduction of size of a tumor associated with said cancer, elimination of a tumor associated with said cancer, prevention of metastatic cancer, prevention of said cancer and stimulation of effector cell immunity against said cancer.

31. (Original) The method of claim 22, wherein said expression of said tumor antigen in a pulmonary tissue by administration of said composition by an intravenous route prevents pulmonary metastatic cancer in said mammal.

32. (Original) The method of claim 1, wherein said mammal has an infectious disease responsive to an immune response, and wherein said immunogen is an infectious disease pathogen antigen.

33. (Original) The method of claim 32, wherein said therapeutic composition further comprises a recombinant nucleic acid molecule having a nucleic acid sequence encoding a cytokine, said nucleic acid sequence being operatively linked to a transcription control sequence.

34. (Original) The method of claim 32, wherein said immunogen is from an infectious disease pathogen selected from the group consisting of bacteria, viruses, parasites, and fungi.

35. (Original) The method of claim 34, wherein said infectious disease pathogen causes a chronic infectious disease in said mammal.

36. (Original) The method of claim 34, wherein said infectious disease pathogen is selected from the group consisting of human immunodeficiency virus (HIV), *Mycobacterium tuberculosis*, herpesvirus, papillomavirus and *Candida*.

37. (Original) The method of claim 32, wherein said expression of said pathogen antigen in a tissue of said mammal produces a result selected from the group consisting of alleviation of said disease, regression of established lesions associated with said disease, alleviation of symptoms of said disease, immunization against said disease and stimulation of effector cell immunity against said disease.

38. (Original) The method of claim 32, wherein said therapeutic composition comprises a plurality of recombinant nucleic acid molecules, each of said recombinant nucleic acid molecules comprising a cDNA sequence amplified from total RNA isolated from an infectious disease pathogen, each of said cDNA sequences encoding an immunogen from said infectious disease pathogen or a fragment thereof and being operatively linked to a transcription control sequence.

39. (Original) The method of claim 32, wherein said infectious disease pathogen is a virus.

40. (Original) The method of claim 39, wherein said virus is selected from the group consisting of human immunodeficiency virus and feline immunodeficiency virus.

41. (Original) The method of claim 32, wherein said infectious disease is tuberculosis.

42. (Original) The method of claim 41, wherein said immunogen is a *Mycobacterium tuberculosis* antigen.

43. (Original) The method of claim 41, wherein said immunogen is antigen 85.

44. (Original) The method of claim 1, wherein said mammal has a disease associated with allergic inflammation and wherein immunogen is an allergen.

45. (Original) The method of claim 44, wherein said therapeutic composition further comprises a recombinant nucleic acid molecule having a nucleic acid sequence encoding a cytokine, said nucleic acid sequence being operatively linked to a transcription control sequence.

46. (Original) The method of claim 44, wherein said allergen is selected from the group consisting of plant pollens, drugs, foods, venoms, insect excretions, molds, animal fluids, animal hair and animal dander.

47. (Original) The method of claim 44, wherein said disease is selected from the group consisting of allergic airway diseases, allergic rhinitis, allergic conjunctivitis, and food allergy.

48. (Original) The method of claim 44, wherein said expression of said allergen in a tissue of said mammal produces a result selected from the group consisting of alleviation of said disease, alleviation of symptoms of said disease, desensitization against said disease, and stimulation of a protective immune response against said disease.

49. (Original) The method of claim 44, wherein said therapeutic composition comprises a plurality of recombinant nucleic acid molecules, each of said recombinant nucleic acid molecules comprising a cDNA sequence amplified from total RNA isolated from an allergen, each of said cDNA sequences encoding said allergen or a fragment thereof and being operatively linked to a transcription control sequence.

50. (Original) A method to elicit a tumor antigen-specific immune response and a systemic, non-specific immune response in a mammal that has cancer, comprising administering to a mammal a therapeutic composition by a route of administration selected from the group consisting of intravenous and intraperitoneal administration, said therapeutic composition comprising:

- (a) a liposome delivery vehicle; and,
- (b) total RNA isolated from a tumor sample, said RNA encoding tumor antigens.

51. (Original) The method of claim 50, wherein said route of administration is intravenous.

52. (Original) The method of claim 50, wherein said therapeutic composition further comprises a recombinant nucleic acid molecule having a nucleic acid sequence encoding a cytokine, said nucleic acid sequence being operatively linked to a transcription control sequence.

53. (Original) The method of claim 50, wherein said RNA is enriched for poly-A RNA prior to said administration to said mammal.

54. (Original) A method to elicit a pathogen-antigen-specific immune response and a systemic, non-specific immune response in a mammal that has an infectious disease, comprising administering to a mammal a therapeutic composition by a route of administration selected from the group consisting of intravenous and intraperitoneal administration, said therapeutic composition comprising:

- (a) a liposome delivery vehicle; and,
- (b) total RNA isolated from an infectious disease pathogen, said RNA encoding pathogen antigens.

55. (Original) The method of claim 54, wherein said route of administration is intravenous.

56. (Original) A composition for systemic administration to a mammal to elicit an immunogen-specific immune response and a systemic, non-specific immune response, comprising:

- (a) a liposome delivery vehicle; and
- (b) a recombinant nucleic acid molecule comprising an isolated nucleic acid sequence encoding an immunogen, said nucleic acid sequence being operatively linked to a transcription control sequence;

wherein said composition has a nucleic acid:lipid ratio of from about 1:1 to about 1:64.

57. (Original) The method of claim 56, wherein said liposome delivery vehicle comprises lipids selected from the group consisting of multilamellar vesicle lipids and extruded lipids.

58. (Original) The method of claim 56, wherein said composition has a nucleic acid:lipid ratio of from about 1:10 to about 1:40.

59. (Original) The composition of claim 56, wherein said liposome comprises multilamellar vesicle lipids.

60. (Original) The composition of claim 56, wherein said liposome delivery vehicle comprises cationic liposomes.

61. (Original) The composition of claim 56, wherein said liposome delivery vehicle comprises pairs of lipids selected from the group consisting of DOTMA and cholesterol; DOTAP and cholesterol; DOTIM and cholesterol; and DDAB and cholesterol.

62. (Original) The composition of claim 56, wherein said liposome delivery vehicle comprises DOTAP and cholesterol.

63. (Original) The composition of claim 56, further comprising a pharmaceutically acceptable excipient.

64. (Original) The composition of claim 63, wherein said excipient comprises a non-ionic diluent.

65. (Original) The composition of claim 64, wherein said excipient is 5 percent dextrose in water (D5W).